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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,195	10/30/2003	Eric M. Leproust	10030416-1	3542

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EXAMINER
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SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,195	<b>Applicant(s)</b> LEPROUST ET AL.	
	<b>Examiner</b> Jason M. Sims	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-15, 22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-15, 22, and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/17/2007 has been entered.

Claims 1-10, 13-15, 22, and 24-29 are the current claims hereby under examination.

### ***Claim Rejections - 35 USC § 101***

Applicant's arguments filed 12/5/2006 have been fully considered but they are not persuasive.

Applicant alleges that the claimed invention satisfies the criteria set out for 35 USC 101 because it produces a nucleic acid sequence that is immediately suitable for use or worthy of further evaluation as suitable for use.

Applicant's allegations are not found persuasive because 35 USC 101 requires that the result of the method steps should produce a physical transformation and if no such result is produced then a concrete, useful, and tangible result should be produced, which has been stated below. Since a physical transformation was not the result of the claimed invention, one would turn to see if a concrete, useful, and tangible result has been produced. Applicant's allegations point to a useful and concrete result, which has not been the subject of the rejection, but the lack of a tangible result as stated below.

Therefore, applicant's claimed invention has not produced a tangible result and has necessitated the instant rejection of the claimed invention under 35 USC 101.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 13-15, 22, and 24-29 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354,

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1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-10, 13-15, 22, and 24-29 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a final resulting step of a physical transformation, if such wording is supported by the instant specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10, 13-15, 22, and 24-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 24 contain the word "evaluation," which has been deemed as vague and indefinite. It is unclear as to what exactly the word "evaluation" refers. Clearer claim wording is required.

Claim 22 contains the word "evaluating," which has been deemed as vague and indefinite. It is unclear as to what exactly the word "evaluating" refers. Clearer claim wording is required.

Claims 2-10, 13-15, and 25-29 are rejected as being dependent on a rejected claim.

***Claim Rejections - 35 USC § 102***

Applicant's arguments and amendment to the claims, filed 12/5/2006, with respect to the rejection of claims 1-3 and 10 under 35 USC 102 (b) have been fully considered and are persuasive. Applicant's amendment to the claims has distinguished the claimed invention from the prior art. The rejection of claims 1-3 and 10 under 35 USC 102 (b) has been withdrawn.

***Claim Rejections - 35 USC § 103***

Applicant's arguments and amendment to the claims, filed 12/5/2006, with respect to the rejection of claims 13-15 under 35 USC 103 have been fully considered and are persuasive. Applicant's amendment to the claims

has distinguished the claimed invention from the prior art. The rejection of claims 13-15 under 35 USC 103 has been withdrawn.

Applicant's amendment has necessitated the new rejection as stated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-15, 22, and 24-29 are rejected under 35 U.S.C. 103(a) as being obvious over Leproust et al. (Pub. No. US 2004/0076964) in view of Tomiuk et al. (December 2001) and further in view of Minor et al. (Pub No. US 2004/0019466).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or

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declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The claims are directed to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe for a target nucleic acid, said method comprising: (a) determining a full length synthesis probability measure for each member sequence of a set of a plurality of candidate probe sequences for said target nucleic acid by evaluation of the susceptibility to depurination during synthesis of each probe sequence; and (b) employing said determined full length synthesis probability measures to select a sequence for use as a substrate immobilized probe for said target nucleic acid.

Leproust et al. teaches claim claims 1-8, 10, 13-15, 22, and 24-28 at the abstract, paragraph [0034], [0042], [0064]-[0075]. Leproust et al., specifically at paragraphs [0064]-[0075] discusses producing a nucleic acid array where the depurination is minimized, which reads on producing a nucleic acid array where a full length synthesis probability measure for each sequence is determined by an evaluation of the susceptibility to depurination. Leproust et al. identifies sequences for use where the susceptibility to depurination is minimized. Moreover, Leproust et al. discusses during a synthesis step an evaluation of the susceptibility to depurination by using a deblocking solution which minimizes



dépurination, reads on depurination susceptibility measure is a deblock dose or parameter thereon. In addition, Leproust et al. discusses thresholds for using such deblocking solutions, which reads on wherein said full length synthesis probability threshold is a total deblock dose threshold and selected sequences have a total deblock dose that does not exceed said deblock dose threshold.

Leproust et al. does not specifically teach identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe from a set of candidate probe sequences and determining a full length synthesis probability measure via an algorithm.

Tomiuk et al. teaches claim 1 at the abstract, page 329, paragraph 1, page 330, first column, paragraph 1 and second column, paragraphs 1-2. Tomiuk et al. discusses at page 329, column 1, paragraph 1 how a successful microarray application requires particular conditions and prerequisites for selecting appropriate DNA probes for an situ nucleic acid synthesis where the probe sequence is selected from a set of candidate sequences. Tomiuk et al. discusses, at the abstract, page 330, first column, paragraph 1 and second column, paragraphs 1-2, probe selection strategies and the use of computer programs for the optimal choice of oligonucleotide sequence selection, which reads identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe from a set of candidate probe sequences and determining a full length synthesis probability measure via an algorithm. Furthermore, Tomiuk et al. discusses the need to pay special attention to sequence characteristics such as, for example, composition and order of bases.

Minor et al. at paragraph [0120] discusses how hybridization can effect the quality of an array application and how selected probes may be inferior due to degradation factors such as a depurination factor specific to a nucleotide "A" in the probe sequence content, which exemplifies the need to consider a depurination factor when identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe for a target nucleic acid.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a depurination factor as taught by Minor et al. for a strategy for selecting probes as taught by Tomiuk et al. because Tomiuk et al. discusses the challenges with selecting probes for nucleic acid sequence synthesis for use in microarray applications where there is a need to pay special attention to sequence characteristics, such as composition and order of bases and such attention to said characteristics can greatly minimize susceptibility to depurination during synthesis of each probe sequence. Furthermore, Tomiuk et al. teaches how using computer programs for optimal choice selection can offer the advantage that probes can be quality-controlled before the spotting process. Leproust et al. already teaches producing a nucleic acid array where the depurination is minimized. However, it would have further been obvious to one of ordinary skill in the art at the time of the instant invention to use a depurination factor, as taught by Minor et al. for use in a probe selection strategy, as taught by Tomiuk et al. to select an optimal sequence from a set of a plurality of probe sequences because Leproust et al. already recognizes the need for minimizing the depurination factor and it is common practice in microarray applications to

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have the need to select an optimal probe sequence for use, therefore, selecting a probe, which minimizes the susceptibility to depurination is selecting an optimal probe sequence for use.

**Conclusion**

No claim is allowed.

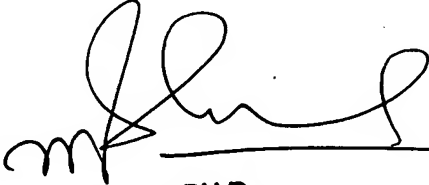
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //



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